PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2007/011278	10.05.2007	11.05.2006

International Patent Classification (IPC) or both national classification and IPC
INV. A61M1/00 A61M27/00

Applicant
IASIS MEDICAL, LLC

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	See form PCT/ISA/210	Lakkis, Angeliki Telephone No. +31 70 340-4136

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2007/011278

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material:

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing:

      ☐ contained in the international application as filed.

      ☐ filed together with the international application in electronic form.

      ☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 58, 59, 60

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☒ no international search report has been established for the whole application or for said claims Nos. 58, 59, 60

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☒ See Supplemental Box for further details

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-57
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-57
Industrial applicability (IA)	Yes:	Claims	1-57
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item III.

Claim 58: Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy, see also remark under VIII, below.
Claims 59, 60: Rule 6.2(a) PCT.

Re Item V.

1 Reference is made to the following documents:

D1 : US 2001/029956 A1 (ARGENTA LOUIS C [US] ET AL) 18 October 2001 (2001-10-18)

D2 : US 2003/040687 A1 (BOYNTON THOMAS A [US] ET AL BOYNTON THOMAS A [US] ET AL) 27 February 2003 (2003-02-27)

D3 : DE 20 2005 019670 U1 (RIESINGER BIRGIT [DE]) 27 April 2006 (2006-04-27)

D4 : WO 01/85248 A (KCI LICENSING INC [US]; HUNT KENNETH WILLIAM [GB]; HEATON KEITH PATRIC) 15 November 2001 (2001-11-15)

2 INDEPENDENT CLAIM 1

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

Document D1 (paragraphs 31, 32, 40, 42, figures 1, 2, 8) discloses (the references in parentheses applying to this document):

A wound therapy device comprising a housing (58) configured to cover at least a portion of a wound; a vacuum source (40ab) in fluid communication with the housing, a liquid collector (10, 50) positioned inside of the housing and in operable communication with the wound, wherein said liquid collector is configured to retain wound exudate while simultaneously communicating negative pressure generated by the vacuum source to the wound.

2.2 Documents D2-D4 also disclose all the technical features of claim 1, see the passages cited in the search report, so that the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT over these documents, either.

3 INDEPENDENT CLAIMS 49. 56, 57

3.1 Independent claims 49, 56, 57, although drafted as independent, comprise essentially all the technical features of claim 1, thus rendering them in fact dependent. Moreover, their subject-matter is not new over either D1 or D2 (see above under 2.1 and additionally for e.g. D1 the features "porous liquid collector" (10), "liquid barrier" (38a), "wound interface" (surface of 10), "seal" (19), "pressure controller" (44), "coupling" (54), "vacuum disperser" (10), "moisture disperser" (10), "skin protection layer" (59). Therefore the present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 49, 56, 57 is not new in the sense of Article 33(2) PCT.

4 DEPENDENT CLAIMS 2-48, 50-55
Dependent claims 2-48, 50-55 do not seem to contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT), see the cited documents and passages and the common knowledge in the field of wound drainage.

Re Item VIII.

5.1 Claim 58 is unclear (Article 6 PCT), in that it defines a method of assembling a wound therapy device which is inherently related to the subsequent utilisation of the device without which the assembly appears not meaningful. The step of using the device is considered as an essential feature and is missing in the claim. Introducing it, however, would introduce a therapeutical step, making this method claim objectable under Rule 39.1(iv) PCT, see III above.

5.2 Independent claims 1, 49, 56, 57 all relate to a wound therapy device, making the

scope of protection unclear (Article 6 PCT).